



Technology Transfer Challenges Between Academia and the Biotechnology Industry

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Technology Transfer Challenges between Academia and the Biotechnology Industry

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A Thesis in the Field of Biotechnology Management
for the Degree of Master of Liberal Arts in Extension Studies

Harvard University

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Abstract

The pursuit of commercializing a novel drug from the technology identified in academia and then transferred to the biotechnology industry for commercialization is a complex endeavor. It faces many technical, managerial, legislative and personnel challenges to overcome. Technology transfers usually occur between two facilities within the same industry since similar practices are shared. However, technology transfers between a university and a biotechnology company involves a more complex structure with unlike processes. Due to this complexity, multiple challenges have arisen that have made technology transfers even more difficult between academia and the biotechnology industry. Pressures have also increased to have success in technology transfers to produce more successful technology transfer deals. Through analyzing specific technology transfer case studies as well as conducting interviews with academia and biotechnology industry experts, we analyze the challenges that are faced with technology transfers between academia and the biotechnology industry. We determined common trends and concepts found in the case studies and discussed common themes in the interviews regarding the challenges of technology transfers. By this, we have determined some recommendations and considerations that could help improve the technology transfer process between academia and the biotechnology industry. These recommendations and considerations are not novel ideas but can provide some clarity and guidance for success in technology transfers.

Dedication

I dedicate this research to the following people that have supported me through throughout this process. To my parents, Mr. & Mrs. Walter and Janet Talley, you have always provided me unconditional love and support. To my brother, Garrett Talley, you have always encouraged me to keep going even when I wanted to give up. To my husband, Timothy Hanlon, you have provided the family balance as well as love and support throughout this process for which I am forever grateful. Finally, to my high school chemistry teacher, Mrs. Loretta Powell, you introduced me to the world of chemistry, and without you, I would have not found my passion for science. Thank you.

Acknowledgments

I would like to thank my Thesis Director, Dr. Cuiru Zhu, for providing me the constant guidance and always helping me through this process. You have been a great mentor always pushing me to the limits. I would like to thank my Research Advisor, Dr. Steven Denkin, for helping me start the thesis process and directing my ideas into a thesis. Finally, I would like to thank all the interviewees that agreed to take time to participate in this research for whom this would not have been possible.

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Chapter I.

Introduction

The technology transfer process for the research, discovery, development and commercialization of biological products between academia and the biotechnology industries have a history of being extremely challenging. The process for the collaboration is insufficient and not well-structured. The time an effort with the collaboration can be wasted. The objectives behind collaborations have proven to be undefined and the intent has a history of not being well communicated between the two industries (Hughes, O'Regan and Wornham, 2009). A survey was taken in 2015 by the America Society for Cell Biology found that two thirds of researchers were unable to reproduce one of their own published results. It has also been reported that a quarter or fewer of high-profile published research papers are irreproducible (Begley, Buchan, and Dirnagl, 2015). It was also reported in an article in 2016 published by Nature: The International Weekly Journal of Science that 70% of research scientists tried and failed to reproduce another research scientists' experiments (Baker, 2016). In addition, it was reported in this article that around 50% to 60% of research scientists failed to reproduce their own experiment (Baker, 2016). This poses a significant problem for technology transfers between the academia and biotechnology industry for it leads to waste of both time and money. These findings showed the lack of the academia's focus to produce reliable quality research. This research aims to examine the challenges of technology transfers between academia and the biotechnology industry by way of analyzing case studies and conducting interviews with academia and biotechnology industry experts. It is

hoped to gain specific insight on these challenges, why these challenges happen and ways to overcome these challenges.

What is Technology Transfer?

Technology transfer is the act of successfully transferring information and technologies from one target group to another. Technology transfer usually involves the licensing of intellectual property rights and extending property rights and expertise (Norman, & Eisenkot, 2017). The technology transfer process between academia and the biotechnology industry refers to transfer of the initial target drug discovered by academia to its reproducibility within the biotechnology industry. This process involves the transfer of knowledge to reproduce the targeted drug and the ownership of the drug discovery that will then enable commercialization of the targeted drug by the biotechnology company (Norman, & Eisenkot, 2017). The goal of technology transfer is to have documented evidence that the targeted drug was transferred successfully, and the manufacturing process of the targeted drug is robust and effective to produce a commercialized scale of operation (Alam & Ahmad, 2013).

Failures in technology transfer often occur from the start of the technology transfer project. A foundation understanding between the two parties is needed and planning is crucial for the success of the technology transfer project. Failures often occur when the university fails to meet the business need of the biotechnology company (Hughes & Wornham, 2009). A gap is sometimes evident between the research theory produced from the university and the business practice that is needed by the biotechnology company for the research. This gap of understanding of both party's intent

for the technology transfers projects have shown to be the demise of failed technology transfers between academia and the biotechnology industry (Hughes & Wornham, 2009).

Technology Transfer Process within Industry

Technology transfers can occur among many groups within the pharmaceutical and biotechnology industries. Most common, technology transfers occur between two facilities within the same industry. The reason is that they usually follow the same practices, policies and guidelines within the industry, making the probability of technology transfer are more successful. Figure 1 illustrates a brief overview of the technology transfer process between two laboratories within the industry (SLAS 2012). It shows the complexities of the process between two laboratories that are involved in the technology transfer as well and level of regulation as the intricacies involved between a technology transfer and the necessary steps needed for success (SLAS 2012). Considering the complexities during technology transfers within the biotechnology industry, the technology transfer failure rate would increase without integral business and well-structured transfer program.

An Overview of the Tech Transfer Process

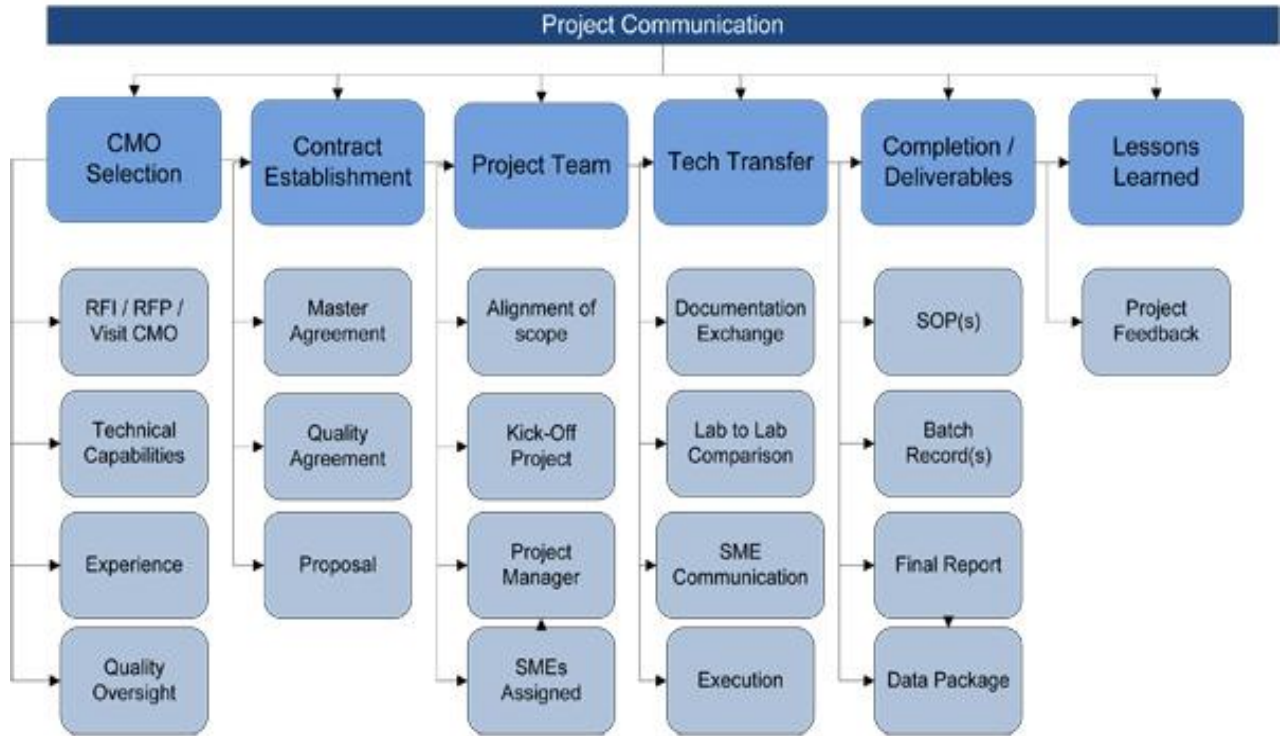


Figure 1: Overview of the Technology Transfer Process within Industry

Figure 1 describes the overview of the technology transfer process within the biotechnology industry from SLAS, 2012.

Technology Transfer Process from Academia to Industry

The technology transfer process from academia industry to the biotechnology industry is different as compared to a technology transfer model within the same industry. As depicted from industry experts, Figure 2 illustrates a traditional model for a technology transfer between a university and a biotechnology company (Godar 2016). As compared to a technology transfer model within the same industry shown in Figure 1, technology transfer between a university and a biotechnology company involves numerous steps and collaborations for its success. It involves many applications and agreements between both parties involving intellectual property with the technology. Within this collaboration, Tech Transfer Offices (TTOs) are usually set up to handle technology transfers between a university and a commercialized biotechnology company (Norman, & Eisenkot, 2017). The TTOs manages the intellectual property (IP), licensing and the contracts. It manages the business and practicalities as well as the industrial and investment communities with the technology transfer (Norman, & Eisenkot, 2017).

Comparing Figure 1 to Figure 2, it can be noted that quality is not an added value of the model for the overview technology transfer process within a university as compared to the overview technology transfer process within industry. The technology transfer process within industry includes quality agreements as part of established contracts as well as demonstration of lab to lab comparison during the technology transfer. In contrast, the overview of the technology transfer process within a university is mostly comprised of business contracts such a, patents and licenses and intellectual property (IP) during the technology transfer. Quality agreements and the demonstration

of reproducing the technology is not a key element in Figure 2 for the model of technology transfer process within a university.

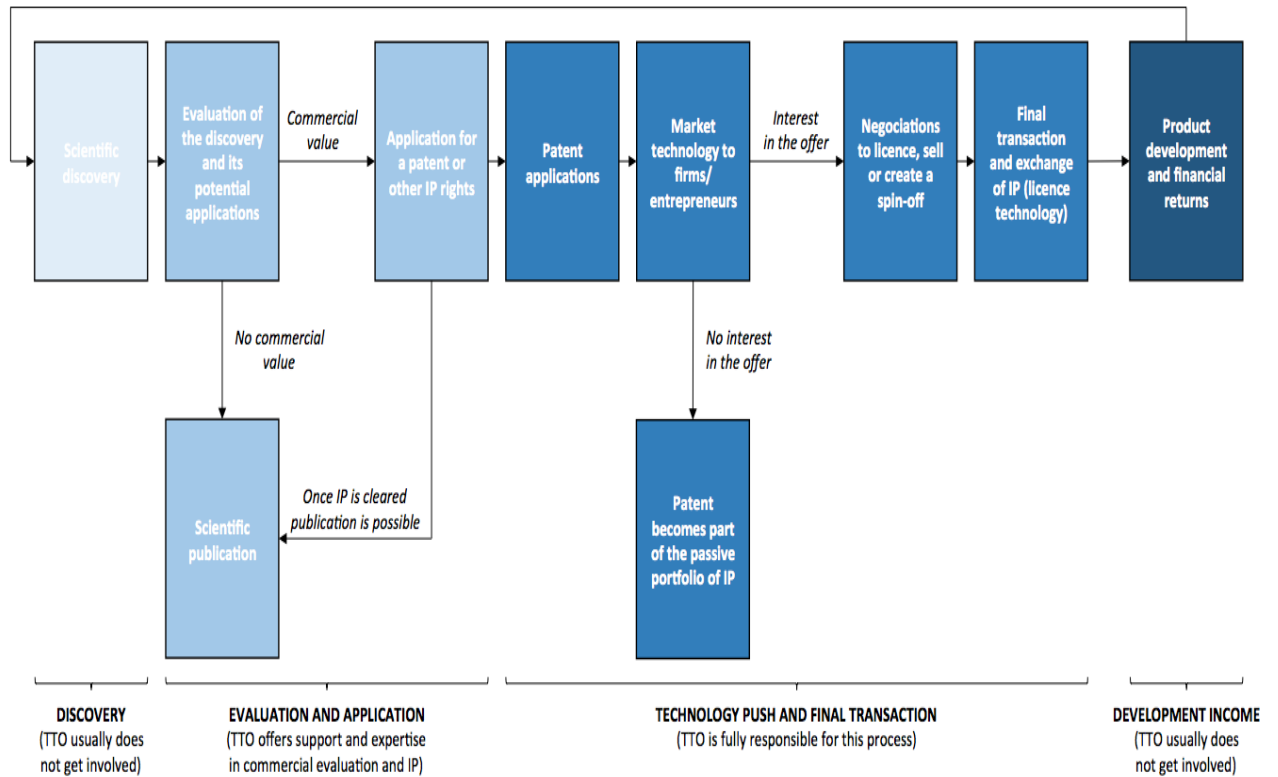


Figure 2: Overview of the Technology Transfer Process within the University

Figure 2 describes the overview of the technology transfer process within the university by Marie Godar from Labiotech.edu, 2016.

Technology Transfer Legislation

The history of technology transfers has been greatly influenced by several key acts of legislation that has enabled its success. The most arguably and important act was the enactment of the Bayh-Dole Act. On July 1st, 1980, the Bayh-Dole Act was passed that prompted to give universities and businesses the right to maintain the title and intellectual property to their federally sponsored innovations. It allowed the inventor to acquire patent rights and protection to the innovation that are federally funded (Greenbaum, 2009). The Bayh-Dole Act was one of the most important pieces of legislature for technology transfer between the university and the industry, since the purpose of the Act was to help lend monetary incentives to for technology transfers. Notably, it was the first legislature that gave universities the incentive to conduct technology transfers with the industry (Greenbaum, 2009).

However, the evolution of the Bayh-Dole Act, enacted in 1980, soon began to cause an unsatisfactory of technology transfers between the university and the biotechnology industry based on the monetary amount lost due the unsuccessful completion of technology transfers (Hammermesh, Lerner and Andrews, 2011). After the enactment of the Bayh-Dole Act, several successes and failed attempts for technology transfers between academia and the biotechnology industry occurred. For example, Carnegie Mellon University made \$25 million from a technology transfer investment with the biotechnology company, Lycos, while Boston University lost \$100 million in a failed biotechnology technology transfer project with the company, Seragen (Hammermesh, Lerner and Andrews, 2011). In addition, between 1991 and 2009, academia research spending for the biotechnology industry tripled from \$1 billion to \$3

billion (Hammermesh, Lerner and Andrews, 2011). However, many biotechnology companies did not license technologies through universities due to issues with the biotechnology companies had with the universities involving technology transfers. In 2002, a survey examined 182 companies which did not license any technologies with universities from 1993 to 2000 (Hammermesh, Lerner and Andrews, 2011). It was noted by the biotechnology companies that the universities over valued the technological invention, underestimated the cost for further development of the technological invention, and required too much monetary incentives for the license. Furthermore, these biotechnology companies felt that there was a clash in culture with the university and that the technology transfer process was too complex and cumbersome that involved unexperienced and unprofessional personnel within the university (Hammermesh, Lerner and Andrews, 2011).

Following the enactment of the Bayh-Dole Act, the Orphan Drug Act passed in 1983. The Orphan Drug Act focused on rare diseases. It gave incentives to companies to invest in research and development on unprofitable drugs (Greenbaum, 2009). The Orphan Drug Act helped build the research in biotechnological sciences and promote the development of specialized medicine that would have been developed in academia. The Orphan Drug Act also helped promote technology transfer between universities and industry for it gave monetary incentives for biotechnological companies to invest in the specialized science from academia (Greenbaum, 2009).

The second most important piece of legislation that focused on technology transfers was the enactment of the Federal Technology Transfer Act in 1986 (Greenbaum, 2009). This Act aimed to institutionalize technology transfer in government

laboratories and allowed federal laboratories in academia to negotiate licenses and patents for innovations discovered in the laboratory (Greenbaum, 2009). As a follow up to the Federal Technology Transfer Act, the Small Business Technology Act, enacted in 1992, increased the opportunity for small businesses, including biotechnology firms, to collaborate with federal research laboratories as well as academia. This further provided both academia and industry monetary incentive for collaborations and technology transfers between academia and industry (Greenbaum, 2009).

Following the enactment of these legislations, a dramatic increase of US patents began to be issued to universities. From the enactment of the Bayh-Dole Act in 1980, the monetary incentives for US universities to invest in research grew which led to the increase of US patents issues to universities. From 1963 to 1980 there were fewer than 100 US patents in US universities. By 1999, there were more than 3,000 US patents in US universities. Figure 3 (Tseng & Raudensky, 2014) depicts a graphical representation of the growth of US patents in universities. Clearly, after the enactment of the Bayh-Dole Act in 1980, US patents dramatically increased providing monetary value to universities for obtaining US patents for drug discovery and allowing for technology transfers to occur from academia to the biotechnology industry for drug commercialization.

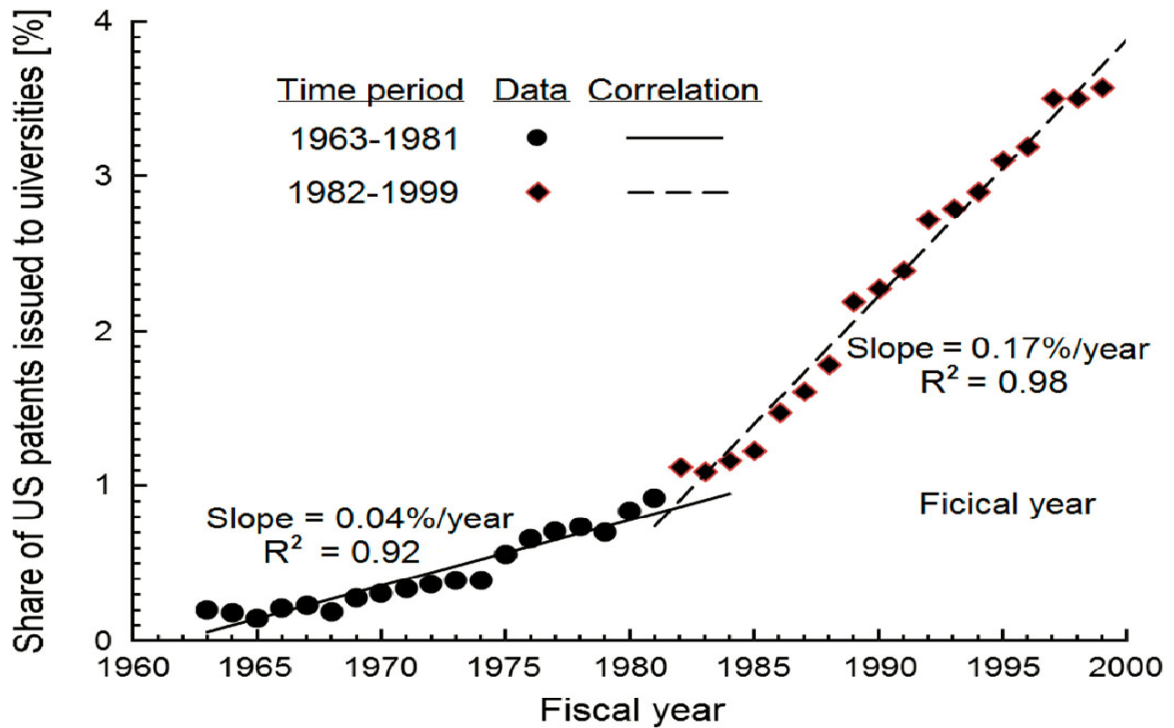


Figure 3: Percentage of US patents issued to US universities from 1963 to 1999

Figure 3 describes the percentage of US patents issued to US universities from 1963 to 1999 by Tseng & Raudensky, 2014.

The National Institute of Health (NIH) publishes an annual report highlighting the technology transfer activities among the NIH TTO's. It highlights analyses of the number of licenses and patents issued for technology transfers. It highlights the number of inventions and intellectual properties developed from academia. It also highlights the current technology transfer collaborations (NIH, 2016). From the 2016 NIH annual report, Figure 4 depicts the number of U.S. licenses versus non-U.S. licenses issued by the TTO's (NIH, 2016). It is interesting from Figure 4 that the U.S. leads in the execution of technology licenses compared to other countries. However, the 2016 NIH annual report does not illustrate the number of successful versus unsuccessful technology

transfers compared to the number of these licenses executed. This data is not available within the 2016 NIH annual report. A representation of the number of successful versus the number of unsuccessful technology transfer collaborations compared to the number of licenses executed within the U.S. and non-U.S. would be beneficial to be included in the technology transfer activities NIH annual reports.

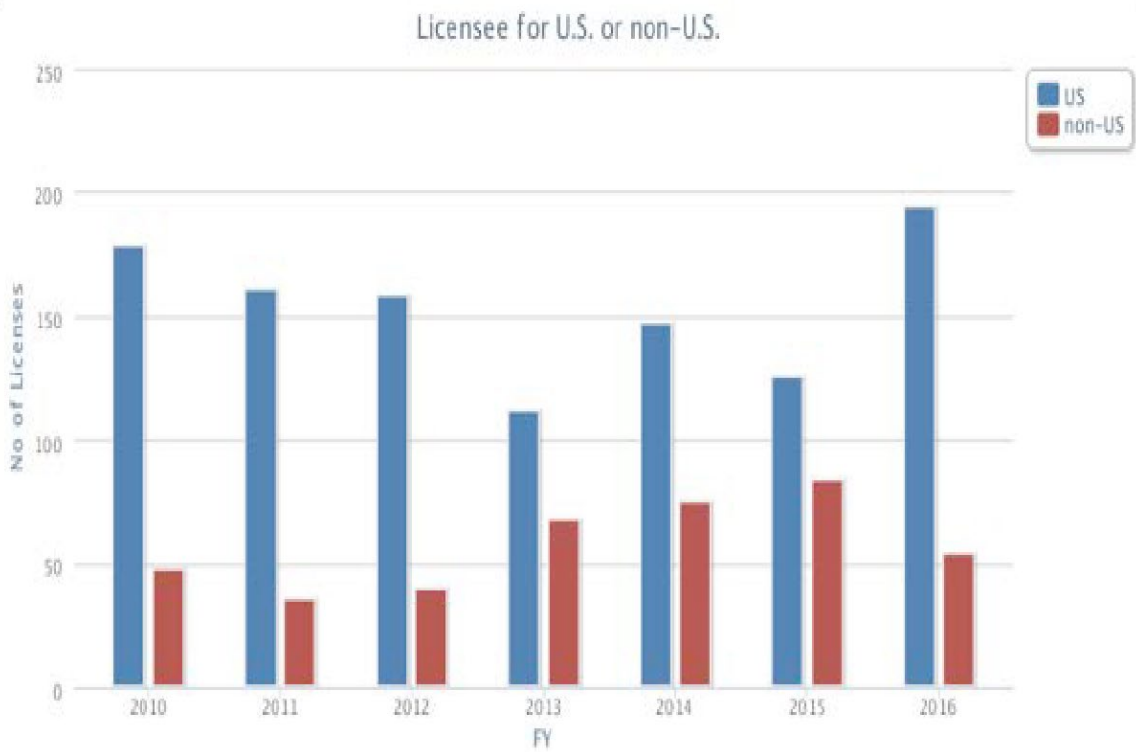


Figure 4: U.S. technology licenses executed versus non-U.S. technology licenses executed from 2010 to 2016

Figure 4 described the U.S. technology licenses executed versus non-U.S. technology licenses executed from 2010 to 2016 from the NIH, 2016.

Pressures for Technology Transfer Success

Technology transfer success did arise from the enactment of the Bayle-Dole Act in 1980. For example, between 1995 and 2009, the number of licenses generated income for the university more than doubled and the number of filed and issued patents more than doubled. In addition, the gross license income grew from \$300 million in 1995 to around \$1.8 billion in 2009 (Hammermesh, Lerner and Andrews, 2011). The Bayle-Dole Act helped fuel the success of TTOs generating deals of technology transfer between universities and the industry. However, as more time progressed, pressures began to increase to keep producing successful technology transfer deals (Begley, Buchan, & Dirnagl, 2015).

As the legislation increased promoting technology transfers between academia and the biotechnology industry, the pressures to have a successful technology transfer also increased. The pressure for a monetary gain became more important than the research discovery itself (Begley, Buchan, & Dirnagl, 2015). In many research laboratories, the incentive to be first in a discovery became more important than the incentive to be correct (Begley, Buchan, & Dirnagl, 2015). An anonymous survey of around 140 trainees at the MD Anderson Cancer Center in Houston, Texas suggested that there was a push to publish which spurred unreliable results. The survey found that the trainees felt pressure to publish uncertain findings, felt pressure to support a mentor's hypothesis even when data did not support it and knew of mentors who required laboratory members to have a high-impact publication before moving on. Quality research was beginning to look like as a luxury rather than a necessity for technology transfer success (Begley, Buchan, & Dirnagl, 2015).

The effects of the enactment of the technology transfers legislations including the Bayh-Dole Act, Orphan Drug Act, the Federal Technology Transfer Act and the Small Business Technology Act was one of the factors analyzed within this research. The research aimed to analyze the enactment of technology transfers to determine if it had any effect on the business success of technology transfers and its impact on the generation of quality research. A comparison of the aspects between successful and unsuccessful technology transfers were analyzed as well as analyzing the key factors of technology transfers that has led success and nonsuccess of technology transfers. Interviews with industry experts within academia and the biotechnology industry were also held to discuss the issues for the successes and failures for technology transfers between academia and the biotechnology industry. The purpose of the interviews was to confirm the results found in the case studies as well as gain further insight of technology transfers between academia and the biotechnology industry.

Technology Transfer Problems

The technology transfer process for the research, discovery, development and commercialization of biological products between academia and the biotechnology industries have a history of being extremely challenging. The process for the collaboration is insufficient and not well-structured. The time and effort with the collaboration can be wasted. The objectives behind collaborations have proven to be undefined and the intent has a history of not being well communicated between the two industries (Hughes, O'Regan and Wornham, 2009). One of the major challenges is the lack of having reproducible results in research within the academia industry (Begley, Buchan, and Dirnagl, 2015). A survey was taken in 2015 by the *America Society for Cell*

Biology found that two thirds of researchers were unable to reproduce one of their own published results. It has also been reported that a quarter or fewer of high-profile published research papers are irreproducible (Begley, Buchan, and Dirnagl, 2015). It was also reported in an article in 2016 published by *Nature: The International Weekly Journal of Science* that 70% of research scientists tried and failed to reproduce another research scientists' experiments (Baker, 2016). In addition, it was reported in this article that around 50% to 60% of research scientists failed to reproduce their own experiment (Baker, 2016). This poses a significant problem for technology transfers between the academia and biotechnology industry for it leads to waste of both time and money. These findings showed the lack of the academia's focus to produce reliable quality research.

Another major challenge has been an effective communication between the academia and biotechnology industry (Birnbaum, 2016). Collaborations are an integral process; every step of the technology transfer process must be transparent and well documented. Lack of value of the academia - industry collaboration, the process of setting up the collaboration and the relationship of the collaboration has all lead to a failure to produce successful technology transfers (Birnbaum, 2016). In addition, the lack of exchange of research information between the two industries has significantly inhibited the success of the technology transfer (Birnbaum, 2016). Suggestions for an effective collaboration between academia and the biotechnology industry include having an open-ended communication network about research ideas and data sharing without having the fear of losing proprietary information. Trust also needs to be built between the two parties as well as an understanding that both parties' interests are maintained (Birnbaum, 2016). Face-to-face meetings and continued status updates about the

technology transfer project also needs to occur to have a successful collaboration. Research suggested that a six-month status report is not enough for an effective communication platform (Birnbaum, 2016).

Technology Transfer Success

The success of technology transfer of innovative research from academia to the biotechnology industry involves many integral business and technical programs to demonstrate the success of a novel biological drug candidate transfer (Norman, & Eisenkot, 2017). Success is defined by the technology transfer project. Success can be defined by the project's milestone achievements within the technology transfer. Success can be achieved within the technology transfer without completely going into commercialization since one milestone can be achieved while another milestone can fail. The criteria for success can be subjective since the motives for the technology transfer might vary among the involved parties.

The business and technical programs involved in a technology transfer includes the development of proof of concepts for drug discovery, implementing product development programs, developing design of experiments for scalable commercialization, developing licensing contracts for intellectual property (IP) and sponsored research agreements (SRAs), as well as forecasting financial models based on project planning and execution (Norman and Eisenkot, 2017). These programs are usually managed through technology transfer offices (TTOs) that work with each partner to help guide the process (Norman and Eisenkot, 2017). Without an established integral business model, mature technology transfer programs, strong collaboration and effective

communication, the successful rate of technology transfer between academia and the biotechnology industry would be very challenging.

Technology Transfer Failures

This research examined the issues that have caused technology transfers to fail between academia and the biotechnology industry. One factor that was analyzed and heavily discussed within this research is the involvement of lack of quality awareness and concepts between the academia and biotechnology industry leading to the inefficiencies of the technology transfer process. Several technology transfers between the academia and the biotechnology industries have shown to have difficulties due to quality issues surrounding the technology transfer. One recent example of an unsuccessful collaboration due to quality was between Novozyme, a Danish enzyme manufacturer and Hebei University of Science and Technology in China (Cyranoski, 2017). This collaboration sought to commercialize a molecule called NgAgo that was to be used to knock out or replace genes in human cells by making incisions at precise points on the DNA. However, doubts emerge through social media and it was found that NgAgo did not produce reproducible results as originally reported in the published paper. The collaboration was then terminated (Cyranoski, 2017). Both time and money were significantly wasted (around US \$ 32 million) on this collaboration all due to the lack of quality management and reproducibility of the research (Cyranoski, 2017).

Within this research, I aimed to answer, what are academia and/or the biotechnology industry doing right and wrong? I hypothesize that the lack of quality research is the main factor for the failures of technology transfers. I propose by

implementing specific guidance's and concepts to the universities can help to increase the success rate of technology transfer processes between academia and the biotechnology industry. This will help universities have more of an understanding of the requirements mandated to the biotechnology industry for the commercialization of biological products.

This research also involved interviews with industry experts within academia and the biotechnology industry to gain input surrounding the issues on the technology transfer processes. These interviews provided pivotal real-life feedback surrounding the knowledge of the technology transfer issues and real-world insight to the success and failures of technology transfers between academia and the biotechnology industry. The interviews provided further insight regarding failures in the technology transfer process between academia and the biotechnology industry and a comparison against the findings of the case studies.

Chapter II.

Research Methods and Limitations

The research methods used within this research are described. The research included analyzing several case studies surrounding the successes and failures of technology transfer between academia and the biotechnology industry. Insight for the reasons behind a successful and failed technology transfer were evaluated in the case studies. In addition to analyzing case studies, this research also included conducting interviews with industry experts from academia and the biotechnology industry that has familiarity with technology transfers. The interviews involved asking the interviews about their experience in technology transfers, their insight into the technology transfer process and their recommendations for a successful technology transfer between academia and the biotechnology industry. The limitations to the research methods are also described that could have hindered the results. These limitations are discussed for each research method.

Case Study Analysis

To evaluate issues associated with technology transfers between academia and the biotechnology industry, it was important to analyze case studies surrounding the success and failure of technology transfers that have occurred between academia and the biotechnology industry. It was important to evaluate the successes technology transfers have had and why these successes have occurred. It was important to compare the

successes of technology transfers and why these technology transfers succeed. It was also important to evaluate what success meant to a case study to help define a failure for a technology transfer between academia and the biotechnology industry. In addition, it was also important to evaluate failures for technology transfers and analyze why these failures occurred. To understand the failures, it was important to analyze the reasons why the failures occurred to understand what could have prevented the technology transfer failure. Within the case study evaluation, the history of the technology transfer process was also assessed to analyze its contribution for lack of supposed quality research within the universities.

A total of five case studies (three successes and two failures) between a university and a biotechnology company that involved technology transfer were analyzed. Within the case study evaluation, the history of the technology transfer process was also assessed to analyze its contribution for lack of supposed quality research within the universities. This includes analyzing the Orphan Drug Act, the Federal Technology Transfer Act and the Small Business Technology Act for its contribution to the lack of quality research produced in technology transfers. The case study evaluations also included correlations between successful technology transfers before and after the passing of these key regulations. Key concepts that impacted the success of the technology transfers were also evaluated in the case studies for reasons why these concepts lead to the failures. A comparison analysis of successful and failed technology transfers was also determined in the case study analyses to foresee underlying causes for a lack of quality research due to the evolution of technology transfers between academia and the biotechnology industry.

Recommendations that could be implemented to lead to more success technology transfers were hoped to be gained in the case study analyses.

The limitations for the evaluation of successful technology transfers versus non-successful technology transfers was the amount of data available for non-successful technology transfers. Universities and companies within the biotechnology industry are less inclined to publish data that showed unfavorable results. Examples of technology transfer failures are limited by the published research retractions that companies release to the public. Technology transfer failures that occur are usually hidden by marketing deploys between universities and company to help lessen the impact it would have for the party.

The availability of unfavorable results from universities is less likely to be published which was also a limitation to the case study analysis. Universities are driven by publishing the “good data”, whereas the unfavorable data is usually hidden in the research or not published. Not able to obtain all the data conducted in a research experiment limited the ability to analyze the quality of research presented. The case study data was limited to providing an accurate account which research data can be reproducible.

We were also limited to deciding how the data is analyzed which demonstrates the success of the research. The statistical analyses have already been provided in the research and we were unaware if any biases were present in the research when it was published.

Interviews

Interviews with industry experts from academia and the biotechnology industry that has familiarity with technology transfers were also conducted. The focus for the interviewee panel was to include experts ranging from drug discovery laboratories, biotechnology start-up companies and biopharmaceutical manufacturing facilities. The main objective for the interviews was to gain valuable input surrounding the issues for the successes and failures for technology transfers between academia and the biotechnology industry. The interviews hoped to gain confirmation from the case study analyses.

The interviews included three parts. The first part of the interview focused on asking the interviewees about their positions, their role and their experience involved in technology transfer activities within either academia or the biotechnology industry. It focused on inquiring about their current tenure in the field, their training within the field, their technology transfer knowledge, and the current state of technology transfers within academia and the biotechnology industry.

The second part of the interview will focus on asking the interviewees about the current technology transfer process and their involvement within this process. It focused on asking about the current technology transfer process, their involvement of technology transfer and the problems they have found with technology transfer within their experience. The questions devolved about their experience in technology transfer, any issues they faced and how these issues were addressed during the completion of a technology transfer project. Questions also included about their experience with the

success and failure of technology transfer projects and the reasons why ones were successful, and others failed.

The last part of the interview focused on about any suggestions the interviewee would recommend for a successful technology transfer project based on their experience. Questions also involved applying best practices including quality and compliance guidelines in an academic setting that could be a consideration to help success in technology transfers. Implementing a required reproducibility assessment during the early phase of the technology transfer project was also inquired to the interviewees for a recommendation.

The information for the interviews were to remain objective and the interviewee does not need to provide any specific names for any technology transfer projects. Only information regarding their experience was required throughout the interviews the discussion remained open-ended between the interviewer and the interviewee.

The research limitations for the interviews was the awareness for the interviewee of the technology transfer issues between academia and the biotechnology industry. The focus of the interviews was to confirm the results found from the case studies. Some of the interviewees might not even be aware of the issues that surround the failures for technology transfers. This limitation was one direct cause for the issues surrounding failures for technology transfers between academia and the biotechnology industry. During the interview, if the interviewee was unaware of the technology transfer issues between academia and the biotechnology industry, I provided the interviewee my analysis and conclusions from the case studies so that they were aware of the issue.

Chapter III.

Results

The results obtained from each research method are discussed. First, the results obtained from both successful and failed technology transfer case studies between academia and the biotechnology industry were documented. Second, the results obtained from the interviews were discussed providing personal insight into the reasons behind successful and failed technology transfers between academia and the biotechnology industry. All results and findings obtained from the case studies and from the interviews were documented.

Technology Transfer Case Study Successes

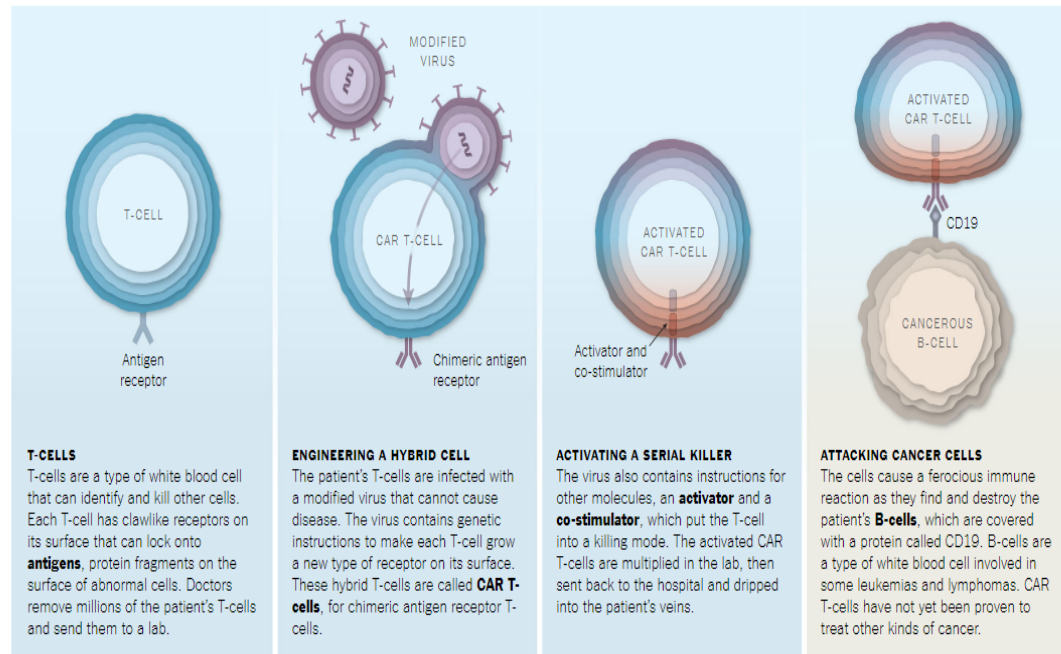
To evaluate the causes for technology transfer failures between academia and the biotechnology industry, it was first important to analyze case studies that had success in their method of technology transfer. Three distant areas of technology were analyzed as part of the case study analysis that included the cancer immunology, gene therapy and cancer therapy. These areas of technology were decided by their complex nature, its specialized nature for therapeutics and its novel approach to success in technology transfer between academia and the biotechnology industry. There are many success examples of technology transfers between academia and the biotechnology industry, but these areas of technology transfer provided more current information of why technology transfers may either succeed or fail.

Cancer immunotherapy is a type of specialized technology harnesses the immune system to battle cancer-stricken tumor cells. Historically, pharmaceutical companies have steered away from developing cancer immunotherapies, due to historical failures of producing a workable treatment as well as the lack of standardizing the methodology to shrink cancer tumors (Couzin-Frankel, 2013). However, recent technology has shown an increase of successes in cancer immunology. One example that has shown promise is the drug called ipilimumab sold by Bristol-Myers Squibb, is a first so-called checkpoint inhibitor for tumor growth. It was demonstrated that tumors shrunk by about half or more in 31% of those with melanoma, 29% with kidney cancer, and 17% with lung cancer while taking the drug ipilimumab. However, the cost for the therapy is high with a cost of around \$120,000 for each course of treatment (Couzin-Frankel, 2013).

The chimeric antigen receptor therapy or known as the CAR-T Cell Therapy is a type of cancer immunotherapy that uses a patients genetically modified T cells to target a specific tumor cell. It is personalized treatment specialized to each patient (Couzin-Frankel, 2013). Figure 5 depicts pictorial representation of how CAR-T cells are manufactured within the cell as well as how they can provide therapeutic treatments. CAR-T cells have shown to kill off B-cells involved with cancers such as leukemias and lymphomas. However, this therapy has not been demonstrated to help treat other kinds of cancers. (Pollack, 2016).

Engineering a Cancer Killer

Doctors are genetically modifying immune cells to hunt down and destroy cancer cells.



By The New York Times

Figure 5: Pictorial Representation of Manufacturing Process for CAR-T Cells

Figure 5 describes the manufacturing process for CAR-T cells from Pollack, August 2016.

Several case study collaborations were analyzed that have occurred between academia and the biotechnology industry to help further research and the development of cancer immunotherapies including the CAR-T Cell Therapy. Table 1 describes the findings for these collaborations and partnerships leading to the success of cancer immunotherapies, including the CAR-T Cell therapy.

Table 1. Case study findings for cancer immunotherapy collaboration

Case Study Focus	Collaborations
<p>Cancer, Immunotherapy, including the CAR-T Cell Therapy</p>	<ul style="list-style-type: none"> • <u>Collaboration #1</u> <ul style="list-style-type: none"> ○ University of Pennsylvania ○ Novartis ((Biopharmaceutical Company) • <u>Collaboration #2</u> <ul style="list-style-type: none"> ○ Kite Pharma, A Gilead Company (Biopharmaceutical Company) ○ National Cancer Institute ○ United States Government • <u>Collaboration# #3</u> <ul style="list-style-type: none"> ○ Juno Therapeutics (Biopharmaceutical Company) ○ Sloan-Kettering Cancer Center ○ Fred Hutchinson Cancer Research Center ○ Seattle Children’s Hospital

Findings

University of Pennsylvania and Novartis Collaboration (Pollack, August 2016):

- University of Pennsylvania was one of the first institutions to use the CAR-T cell therapy technology from a patient's own cells to help kill cancer.
- In 2011, Novartis licensed the rights for CAR-T cell therapy technology. This caused a turn of events for the biotechnology industry since it was the start of buying therapies that are more specialized and not mass marketed.
- There were more collaborations on these types of immunotherapies that included licensing with University of Pennsylvania and National Cancer Institute.

Kite Pharma (A Gilead Company), the National Cancer Institute and United States Government Collaboration (Moas, 2016), (Pollack, August 2016):

- A distant collaboration occurred between Kite Pharma (A Gilead Company), the National Cancer Institute and the United States Government to help get a cell therapy for cancer immunology approved.
- The United States Government supported research using federal laboratories and federal funding
- According to the institutes involved in the collaborations, these successes were not about the monetary gains but getting a drug cell therapy approved.
- These successes would not have happened without funding and support from the United States Government.

Generalized Partnerships for Cancer Immunotherapies (Pollack, August and December 2016), (Moas, 2016):

- There was much debate with using tax payer's money to fund highly specialized high cost drug therapies.
- Partnering deals with public sector were influenced by the Bayh-Dole Act and other Acts in the 1980s. The influence of these acts was first questioned when tax payer money was being used to fund drug research.
- Debates came about targeting if drug companies were charging too much to personal gain when using tax payer's money to fund such specialized drug research as high costs including the CAR-T Cell Therapy.
- However, these acts have been credited to jump start the biotech industry.
- It was discussed to let the drug company set the price to take the technology to market, but the price must be reasonable. There needs to be competition to help drive success of the technology.
- Royalties can be obtained from the public sector to balance the cost of the technology.

- Public sectors should not take equity positions in the drug companies to avoid conflict of interest. However, academia has taken equity positions in the drug companies which has caused issues with conflict of interests.
- Success in human patients involved cancer immunotherapies have been found early on in clinical development showing lots of promise in this field.
- Partnerships were not only from the researcher to the company but multiple layers of collaborations and partnerships with private and public sectors with academia, research centers and industry. This is very important to have success in these types of drug therapies. Success cannot be done alone.
- The use of government funded research facilities has proven to be invaluable for knowledge to getting a therapy developed. Risk must be taken to have success.
- Cells used for immunotherapies are harvested from own patients involved in cancer immunotherapies, not generically made, which helps to understand how the technology works in the patient. How the cells are manipulated and grown is also very well understood.
- The use of government funded research facilities has proven to be invaluable for knowledge to getting a therapy developed. Risk must be taken to have success.
- Building a robust intellectual property (IP) group with scientific leaders helps drive success for gene-based cellular immunotherapy. Strong science and business person partnership with research center is key to success.
- The most important drug therapies moved to commercialization have some public sector involvement (around 47.8% involvement).

Table 1 describes the case study finding for cancer immunotherapy collaborations including the CAR-T cell therapy collaboration from Moas, 2016 and Pollack, August and December 2016.

In addition to the collaborations for cancer immunotherapies, an additional case study was analyzed between academia and the biotechnology industry for gene therapy. Gene therapy is the transfer of working gene into specific cells to repair a faulty gene (Sudip et al., 2013). The technology is used to repair a faulty gene or to introduce a new gene whose function is to cure or modify a type of condition. The delivery system for gene therapy includes viral vectors that delivers a therapeutic gene into the patient's target cell to help the cell produce working proteins and cause the cell to return to a

normal condition (Sudip et al., 2013). Figure 6 depicts pictorial representation how a viral vector carries a gene of interest into a host cell to help the cell produce protein by normal a normal gene.

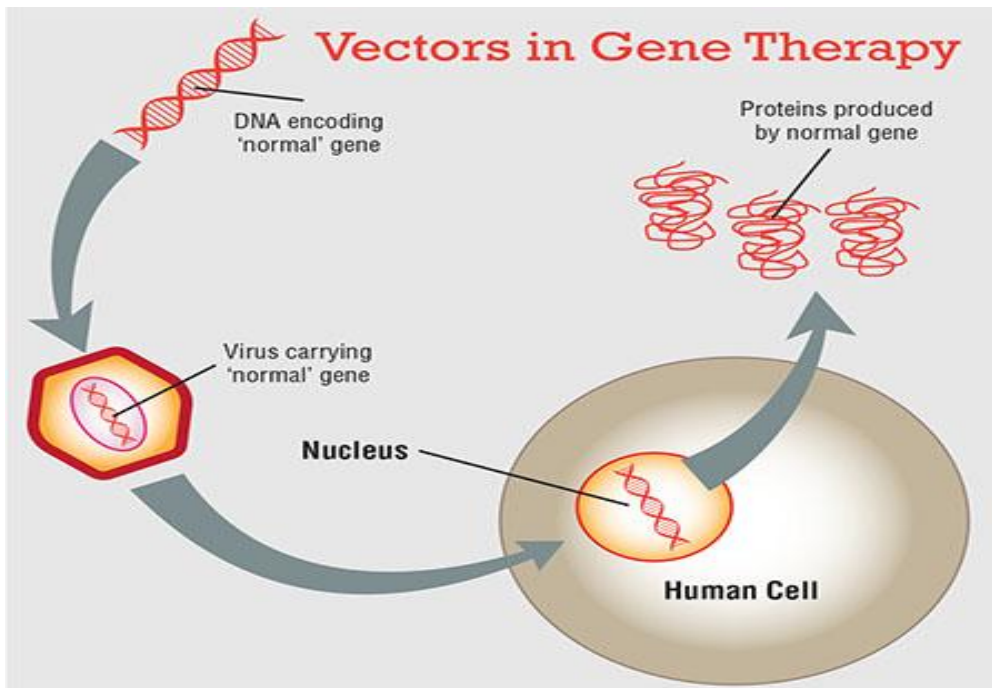


Figure 6: Graphical Representation for the Gene Therapy Process

Figure 6 describes the process of gene therapy for how viral vectors are used to deliver a gene of interest into a cell from Kay, 2017.

Table 2 describes the case study findings for specific gene therapy collaboration.

Table 2. Case study findings for a gene therapy collaboration

Case Study Focus	Collaborations
Gene Therapy	<ul style="list-style-type: none"> ● Collaboration <ul style="list-style-type: none"> ○ University of Pennsylvania ○ Children's Hospital of Philadelphia ○ Spark Therapeutics (Biopharmaceutical Company)
<p style="text-align: center;"><u>Findings</u></p> <p>University of Pennsylvania, Children's Hospital of Philadelphia and Spark Therapeutics Collaboration (Sagonowsky, 2017), (Reddy, 2018):</p> <ul style="list-style-type: none"> ● This successful collaboration won approval for the first gene therapy, Luxturna: ● It is a type of gene therapy to treat vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have enough viable retinal cells, a condition leading to total blindness in most patients. ● The cost of the therapy is \$425,000 per eye which is the most expensive dose of a drug in the US. ● The approval of this gene therapy is the collection of 25 years of studies on congenital blindness by a married-couple team at the University of Pennsylvania and Children's Hospital of Philadelphia. These studies started out with in mice and dogs. ● The success of the approval and commercialization for this gene therapy was not about the technology transfer but about partnerships. 	

Table 2 describes the case study findings for a gene therapy collaboration from Sagonowsky, 2017 and Reddy, 2018.

Lastly, a case study was analyzed between academia and the biotechnology industry for a cancer therapy, specifically for prostate cancer. Table 3 describes the findings for this collaboration.

Table 3. Case study analysis for a cancer therapy collaboration

Case Study Focus	Collaboration
Cancer Therapy	<ul style="list-style-type: none"> ● <u>Collaboration</u> <ul style="list-style-type: none"> ○ University of California, Los Angeles (UCLA) ○ Medivation (Biopharmaceutical Company) ○ Aragon (Biopharmaceutical Company)
<p style="text-align: center;"><u>Findings</u></p> <p>University of California, Los Angeles (UCLA), Medivation and Aragon Collaboration</p> <p>(Bennett, and Ingason, 2014), (Patel, et al., 2014), (Medivation, Inc, et al., 2016)</p> <ul style="list-style-type: none"> ● A successful academia and industry cancer drug therapy collaboration for the development and commercialization the prostate cancer drug, Xtandi. ● Even though this was a successful technology transfer between academia and the biotechnology industry to produce a technology into a drug communication, this case also demonstrated some of the problems with technology transfer. There was a lawsuit between the companies Medivation and Aragon for rights to the technology for intellectual property (IP). ● This involved the following issue: <ul style="list-style-type: none"> ○ The same professor at UCLA developed very similar compounds for prostate cancer that UCLA licensed to another pharmaceutical company called Aragon. Medivation sued and claimed that under its agreement with UCLA, it should have been entitled to those technology compounds as well. UCLA, however, won the lawsuit. It was also found that the company Medivation had underpaid it intellection property (IP) royalties. Pharmaceutical company Johnson and Johnson bought Aragon and the drug, Erleada, was also developed for prostate cancer and is now on the market. 	

Table 3 describes the case study analysis for cancer therapy collaboration from Bennett, and Ingason, 2014, Patel, et al., 2014 and Medivation, Inc, et al., 2016.

Technology Transfer Case Study Failures

It was then important to analyze case studies that had failures in their method of technology transfer. The failures focused on clinical trial failures and not failures in the licensing part of the intellectual property (IP) between a university and a biotechnology industry. The reason was due to the limitation to analyze a case study for a failure due to licensing. A university is licensing a technology target or even a concept which is not an actual drug. In addition, to obtain examples for licensing failures is usually proprietary to the institution and not publicly accessible. Therefore, it is difficult to analyze licensing failures between a university and a biotechnology company. Consequently, case studies involving clinical trial failures were analyzed.

Three distant areas of technologies were analyzed for technology failures as part of the case study analysis. First, a case study for stem cell therapy was analyzed. Stem cells are a specialized type of cell that can differentiate into many different types of cells (Biehl and Russell, 2009). As stem cells divide, they have the potential to remain a stem cell or become another type of cell with a more specialized function within the body such as a muscle cell, brain cell or a bone cell. Stem cell therapy is the use of these stem cells to correct or repair a type of dysfunction by regenerating a specific cell (Biehl and Russell, 2009). Table 4 describes the findings for this collaboration.

Table 4. Case study findings for a stem cell therapy collaboration

Case Study Focus	Collaboration
Stem Cell Therapy	<ul style="list-style-type: none"> ● <u>Collaboration</u> <ul style="list-style-type: none"> ○ Stanford University ○ StemCells Inc. (Biotechnology Company)
<p style="text-align: center;"><u>Findings</u></p> <p>Stanford and StemCell Inc. Collaboration (Shanks, 2016), (Keshava, 2016)</p> <ul style="list-style-type: none"> ● StemCell Inc spent over a decade and tens of millions of dollars trying to develop stem cell therapies. ● They failed to move treatments through clinical trials for treatments for spinal cord injuries, Alzheimer’s disease, dry aged -related macular degeneration disease. ● It was once a prominent investor of California Institute for Regenerative Medicine (CIRM), a government agency funded by the state’s taxpayers for further stem cell research. ● Its conflict relationship with CIRM was a contributing factor to its decline. <p><u>Background of the government agency CIRM</u> (Shanks, 2016), (Keshava, 2016):</p> <ul style="list-style-type: none"> ● In 2005, voters agreed to establish the California Institute for Regenerative Medicine (CIRM) to provide up to \$3 billion for stem cell research. ● CIRM faced challenges of transitioning its scientific programs and partnerships towards bringing treatments to the market. This included to help speed promising stem cell therapies into actual medicines available to patients. ● Problems also faced CIRM with its perception of conflicts of interests with having too many board members represent organizations that receive CIRM funding or benefit from that funding. ● CIRM requested an external review board to committee to independently review its programs, operations, and strategies. It was recommended that CIRM build an external board, comprising people who have expertise in the scientific, clinical, industry, and regulatory facets of stem cell biology and cell-based therapies. This external board would help to ensure CIRM is appropriately funding the best science, provide input about which discoveries should progress to trials in patients, and help outline how to engage industry partners in costly, time-consuming drug development. ● The decline of StemCells, Inc happened during a major conflict-of-interest dispute happened when the appointed CIRM president resigned and joined the board of StemCells Inc in 2014. ● This demonstrated a serious conflict-of-interest since StemCells, Inc is funded by CIRM by receiving over \$250 million dollars including over \$40 million dollars for a new building in taxpayers’ money. 	

Table 4 describes the case study analysis for a stem cell therapy collaboration from Shanks, 2016 and Keshava, 2016.

Lastly, a case study was analyzed between academia and the biotechnology industry for the involvement of using beta amyloid inhibitors to help cure Alzheimer’s disease. Beta amyloids is a type of protein aggregate that has been associated to cause numerous chronic, neurodegenerative diseases. Beta amyloid inhibitors is a molecule that hopes to prevent the protein aggregate and to lessen the effects of the neurodegenerative disease including Alzheimer’s disease (Velander, et.al., 2017). Table 5 describes the findings for this collaboration.

Table 5. Case study findings for a beta amyloid inhibitors collaboration

Case Study Focus	Collaboration
Beta Amyloid Inhibitors	<ul style="list-style-type: none"> • <u>Collaboration</u> <ul style="list-style-type: none"> ○ Harvard University ○ Prana Biotechnology (Biotechnology Company)
<p style="text-align: center;"><u>Findings</u></p> <p><u>Harvard University and Prana Biotechnology Collaboration</u> (Vrinda, 2014):</p> <ul style="list-style-type: none"> • Prana Biotechnology was co-founded by an Alzheimer’s expert professor from Harvard University who is interested in the roles of metals like copper play in amyloid plaque formation. • It is thought that the onset of Alzheimer’s is caused by beta amyloid plaques in the brain. • In 2014, Prana Biotechnology’s first Alzheimer’s drug failed the phase 2 trial. The setback in its Alzheimer’s study raised concerns that the company will have to raise funds to conduct a larger trial since failing it its phase 2 trials. • There were also concerns to find it difficult to attract a partner for the drug. It was stated that Prana Biotechnology would “need to do a trial that would show a meaningful clinical benefit rather than just a structural change in the brain without an improvement in quality of life” (Vrinda, 2014). • Prana Biotechnology stated the drug did not demonstrate statistically significant reduction in the levels of beta-amyloid plaques in the brain when compared with a placebo in patients with a mild form of the condition. • Prana Biotechnology also stated that the drug did not improve brain metabolic activity, cognition and function in the phase 2 trial study. 	

Table 5 describes the case study analysis for a beta amyloid inhibitors collaboration by Vrinda, 2014.

Interviews

To gain personal insight surrounding the issues for the successes and failures for technology transfers between academia and the biotechnology industry, we conducted eight interviews that included both academia and industry experts. The interviews needed to be conducted with expertise across the spectrum of the technology transfer process to minimize the subjectivity on why technology transfer may either succeed or fail. Expertise obtained in the interviews ranged from scientific pioneers in academia to quality leaders in the commercial phase of the biotechnology industry. Expertise was also obtained in the middle with leaders of technology transfer between academia and the biotechnology industry that included expertise in process and analytical development in technology transfer as well as technology transfer manufacturing. Three interviews were also conducted in biotechnology industry leaders with over 20 years of experience that had success with biotechnology startup companies with direct involvement in success of technology transfer. Both qualitative and quantitative data were collected during the interviews, however, the focus was more about having an open-ended discussion about the success and failures of technology transfers between academia and the biotechnology industry. Attention was most focused to the interviewees personal experience, thoughts and input on the technology transfers. This allowed the interviewees to have free rein to express their thoughts. An interview questionnaire with interview questions was presented to the interviewees to help guide them through the interview. However, it was made known prior to the interviewees that these questions do not have to answered in order that an open-ended discussion was more warranted for the interview. Emphasis was mostly placed on discussing questions relating to the interviewee's experience and

involvement with the technology transfer process as well as their suggestions they would recommend for a successful technology transfer project.

Interview Findings

Table 6 represents the findings during the interviews. The table gives an overview on the sector each interview belongs to, their role and experience in their sector and the findings that came about during the interview.

Table 6. Interview findings

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Biotechnology Industry	Quality Control, Validation	Associate Director	Analytical Method Technology Transfer	+20 years
<p style="text-align: center;">Findings</p> <ul style="list-style-type: none"> ▪ One of the most challenging factors is time for a successful technology transfer. ▪ Planning is a key element for success ▪ Preparedness is a must to get it right and to do it fast. ▪ Technology Transfer needs to have room for robustness. The involves movement in test method transfer for analytics. ▪ Comparability is key for technology transfer to decide how much movement is allowed in the analytics for technology transfer. ▪ Specificity needs to be tested early to demonstrate comparability for the analytics between laboratories during technology transfer. ▪ Robustness and reproducibility are most important aspects that need to be determines for success of technology transfer for analytics. ▪ Results must be reproduced at least three times for the data to be real during analytical technology transfer. ▪ A technology transfer strategy document should be a requirement early in the process between the sending and receiving units. ▪ There should be a requirement to do more analytical studies in the development laboratory. This should be part of the technology transfer strategy document ▪ Risk should be more quality based. ▪ Research laboratories are more eager to transfer technology prior to demonstrating technology that is transferable. ▪ Training is a major gap in technology transfer for analytics. This is caused by being too rushed and pushed to be “Right First Time”. ▪ There is a lack collaboration whereas the sending unit SMEs needs to go to the receiving unit during the technology transfer to provide guidance and training. ▪ Best way to have success in technology transfer: <ul style="list-style-type: none"> ○ Develop your materials list first ○ Understand the technology being transferred and how it works ○ Try to reproduce the technology being transferred early in the process. ○ To have success, commitment is a must for all parties involved. ▪ Need to have contingency plans for failures with the technology transfer project. These contingency plans need to be outlined and documented in a Technology transfer strategy plan. ▪ Academia shows promises but there is no proof yet on their success. ▪ There needs to be an indicator in academia to demonstrate that their technology works and can be transferable ▪ There needs to be a standard peer review of research technology and data with expectations of current Good Document Practices (cGDP). 				

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Biotechnology Industry	Quality Assurance, Validation	Director	Facilities, Equipment and Utilities Technology Transfer	+20 years

Findings

- The key issue with technology transfers is not defining expectations appropriately between the sending unit and the receiving unit.
- More risk management oversight is needed in the technology transfer process. This includes a more robust and detailed gap analysis for materials and equipment needed for the technology transfer.
- There are different levels of expectations. Academia does not forward think.
- More granularity is needed within academia. The gaps between the sending unit and the receiving unit needs to be more understood at a very granular level.
- Academia needs the following upfront to have more success in technology transfers:
 - appropriate controls defined in their technology
 - More peer reviews of research papers
 - Verify equipment calibration used in research
 - Understanding of change management
 - Have some type of quality management system for development work
 - Understand data integrity concepts
- A recommendation would be to implement Best Practices within academia
- Need to define success upfront in the technology transfer project to have better outcomes.
- Need to have a defined process with goals and defined success criteria upfront.
- Need to have the sending unit involved, responsible and accountable to the end of the technology transfer project.
- Having some type of management system in the beginning would be an advantage. This can include:
 - knowledge management (document management, including GDP)
 - Understanding and documenting the specifications for materials, equipment, instrumentations
 - Understanding Critical Process Parameters and or Quality Critical Attributes
 - Having written/version-controlled procedures
 - A process for change management

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Academia Biotechnology Industry	Business Developer Academia and Industry Technology Transfer	Industry and Academia Senior Leader	Technical and Business Developer for Technology Transfer	+20 years

Findings

- Expectations is key and needs to be defined first between both the university and the company. The same language needs to be spoken with these expectations. Both parties need to be on the same wavelength to have success in the technology transfer.
 - Industry must lower their expectations and be more proactive and spend more time in the technology transfer process.
 - Academia must be active in the technology transfer process and be practical on the expectation. The type of technology being transferred can dictate the expectations.
- Involve the researcher within the technology transfer as much as possible for success.
- Define the intellectual property (IP) carefully within academia. Define it as either a target or lead molecule that will be involved in the technology transfer. Target technology is harder to develop and transfer than a lead molecule. Sometimes there is only one research paper available for the technology.
- Define the milestones of the technology transfer projects and have agreement on them between the university and the company.
- Before signing a technology transfer contract, verify that results can be reproduced in some manner.
- Collaborations are key for success.
- Risk management needs to be developed in the technology transfer process. Scenario planning needs to be well developed to mitigate risks.

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Biotechnology Industry	Analytical, Science and Technology	Director	Analytical Development Technology Transfer	+20 years

Findings

- Research laboratories need more experience about industry. A guidance document for research laboratories about industry would be helpful.
- The success for technology transfers comes down to the agreements and its ownership. It's all about the agreement. Defined ownership is a problem.
 - Quality Agreements are needed to help mitigate this issue.
- Research laboratories lack the skill set for industry.
- Effective communication is key for success. A project manager and a kick off meeting with all parties should occur. The research scientists should be involved every week and there should be a defined group structure for the technology transfer project to have success.
- More training is needed for the receiving laboratory on how to analyze the technology being transferred. This includes performing more shake-down runs by the receiving laboratory with guidance from the sending laboratory.
- A reason for a technology transfer failure is that the receiving unit did not report back their results to the sending unit, therefore, interpretation of the results could not be determined properly.
- The sending unit should always be involved in quality to the receiving unit. This is not always the case that has led to technology transfer failures.
- A master quality agreement needs to be in place between the sending unit and the receiving unit. The best practice is when quality is not met in the receiving unit, the receiving should work with the sending unit to obtain quality standards. This should be in a master quality agreement for the technology transfer project.
- Transfer of academia technology the industrial research is more acceptable. Transfer of academia technology to quality control is impossible.
- Agreements are everything. Business agreements should also be in place that ensure that the principal of the science for the transfer of technology and that collaboration is obtained.
- Reproducibility is an issue. To help reproduce the technology, follow the thing track of the published paper to make it work. If unsuccessful to reproduce, follow the concept of the research paper by using different molecules. This can help technology transfer from an academic setting to an industrial research laboratory.
- The discovery phase is the hardest part of the process, but expectations needs to be set early on in the process between parties.

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Biotechnology Industry	Manufacturing Technology Transfer	Director	Manufacturing Developer Technology Transfer	+20 years

Findings

- Lack of training is an issue with technology transfer failures. Training is evolved from experience within the industry.
- The enhancement of training tools such as Best Practices and white papers could better the success of technology transfers.
- Learning is using performed by common, shared information with others through conferences.
- Robustness is needed for the technology. Points of failure for the process of reproducing the technology is usually not well understood leading to technology transfer failures.
- There is a lack of development within academia and research laboratories to understand where the process for producing the technology could failure.
- There is a lack of understanding the scalability of the technology process within academia and research laboratories.
- Tools and structure for what is known and not known when transferring the technology including the intellectual property is key.
- An information flow path needs to be structure and defined during the process for transferring technology.
- Some raw materials used on academia can't be used in the industry. Need more guidance on the selection of raw materials.
- Academia sometimes overengineers the technology process leading to failures. Academia makes the technology so specialized it can be manufactured.
- Habits form in academia research that go into the technology process and not documented. There is a lack of standard platforms for technology processes, manufacturing and transfer.
- The planning phase is key to success and risk needs to be analyzed for the technology transfer.
- Records of the technology need to stand on their own during the technology transfer between the sending unit and the receiving unit.
- The need to define technology transfer between all parties is needed to have success. This includes defining quality attributes.
- Quality guidelines would be great to have but may be impractical. Analytical test methods are not well developed during the technology transfer phase between academia and industry.
- Performing a Gap Analysis, Gap Assessment and Risk Assessment are all imperative to understand what is important to have success.
- More awareness of technology transfer within the industry business in all groups could lead to more success. Technology transfer incorporates into all groups within industry.

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Biotechnology Industry	Process Development	Director	Process Developer Technology Transfer	+20 years

Findings

- Training for technology transfer is not well defined. It is hard to have training since each type of therapy differs for technology transfer. Case studies is the best way to learn technology transfer until processes are well characterized and defined for standard platform technologies.
 - Gene therapy is so new that specific training is impractical. Both academia and industry both need training on gene therapy processes.
- Feedback loops and lessons learned need to be more communicated between academia and industry. There is no mechanism for this to happen during technology transfer.
- Issues with technology transfers leading to failures:
 - No mechanism developed on the process
 - Control parameters not well defined
 - Technology not well characterized
 - Technology not scalable
 - Academia and industry not aware technology transfers are being processed in contract development manufacturing organizations (CDMO).
 - Academia and industry not aware on how to remove impurities within the process. This leads to issues with transferring the process.
- These issues are being passively address in conferences. There has been cross talk what exists, but it has not been discussed what doesn't work.
- It is difficult to have these discussions on these issues due to legal reasons for sharing the technology. This clouds the feedback loops due to protecting trade secrets. However, in turn, this can impede the success for technology transfers.
- Challenges:
 - How to overcome the poorly developed technologies from academia
 - Academia has shown the design of scientifically sound therapies but has not shown how to develop the therapy in manufacturers.
 - Lack of experience. Experience helps bridge the gaps of what works and what doesn't work.
 - There is no quality aspect in academia. There is no level of control in academia.
 - Industry is hiring personnel with academic backgrounds with strict science backgrounds but no knowledge in the industry.
- Recommendations:
 - Have written guidelines for efficiency between both parties.
 - Work on a methodology for defining potency and purity in academia. This can greatly help alleviate rework and failures during the transfer process.
 - The technology transfer process needs to start with the analytics. Determining the attributes and small changes in the technology is key. Standardizing the analytics by assessing the different methods and involving a reference material that is available to industry is imperative to help transfer the technology to industry.
- It comes down to the CDMO to educate academia and industry about how to produce the technology to have success.

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Academia Biotechnology Industry	Business Developer Academia and Industry Technology Transfer	Industry and Academia Senior Leader	Technical and Business Developer for Technology Transfer	+20 years

Findings

- There is a lack of training on how to do technology transfers. Most of the training is all on the field.
- The current state of technology transfers within academia and the biotechnology industry is stagnate. The reasons are as follows:
 - There is no motive to do technology transfer between academia and the biotechnology industry.
 - Technology transfer does not teach what will happen to the technology after it leaves the university.
 - Academia does not know how to translate their technology from research to the market.
- Recommendations to academia to have success in transferring technology:
 - Recognize that you have technology and don't publish it.
 - When starting the process wanted to sell the technology, meet with finance. Universities don't know how to invest money very well.
 - Have research personnel invest in learning management and business skills to help drive the success for the selling and transferring the technology
 - Find a mentor to help with the process
 - Collaborate as much as possible to have success in technology transfer
 - Find an industry that would like to try your technology.

Interviewee Sector	Interviewee Focal Area	Interviewee Level	Interviewee Association	Interviewee Experience
Academia Biotechnology Industry	Business Developer Academia and Industry Technology Transfer	Industry and Academia Senior Leader	Technical and Business Developer for Technology Transfer	+20 years
<p style="text-align: center;">Findings</p> <ul style="list-style-type: none"> ▪ To have success in technology transfer, share common practices, but “hide” the data. Nondisclosure agreements need to be in place with all collaboration parties. The data needs to be protected and not be reversed engineered. ▪ Academia is aware what is needed for biological products to technology transfer. However, biological products that have a higher volatility is harder to transfer. This includes gene therapy and cell therapy medicines. ▪ A process for commercialization, not just discovery, is needed between academia and industry for success in technology transfer. The technology is not scalable in academia. To help alleviate the scalability issues of the process for the technology, define the challenges first and define the knowledge gap. The scalable and GMPable processes need to be thought of in the sending unit. ▪ Industry needs to know that they will need to rework the process during transfer many times. Industry needs to accept this responsibility. ▪ Industry knows the best was to test the technology. Academia does not. Industry needs to determine how reliable the data is from academia for the technology. ▪ The issue with technology transfers is a business development issue and not a technical issue. <ul style="list-style-type: none"> ○ The longer the technology takes to be transferred and developed, the less value it has for return on investment. ○ A business strategy needs to be in place for both the university and the company. ○ It needs to be decided who will want to take the most risk on the technology transfer. ○ The technology transfer is not about the details but more about strategy for success. 				

Table 6 describes the interview findings regarding challenges of technology transfer between academia and the biotechnology industry.

Chapter IV.

Discussion

The results and findings from both the case studies and the interviews are examined. Trends and concepts for a successful and failed technology transfer among the case studies are discussed. The impact of legislation on technology transfers for the case studies are also described. The themes that were encountered during the interviews regarding the challenges of technology transfers are examined. By analyzing the results and the findings for both the case studies and the interviews, a list of considerations and recommendations to help have a successful technology transfer between academia and the biotechnology industry is obtained.

Case Study Analysis

By examining the results obtained from the case studies and the responses given by the interviewees, several discussion points can be made. For the case studies, we examined any trends that were found for the success and the failure of technology transfers, the impact of the legislative history for technology transfers, key concepts that could have impacted the success and failure of the technology transfers and possible recommendations that have come out from the case study results to help improve technology transfers.

Both trends and concepts were a theme among the results for the case study analyses. Trends were evident among both successful technology transfers and failed

technology transfers. In addition, concepts that impacted the success and failure of technology transfers were evident within the results. Table 6 describes these trends and concepts that were found among the case study analyses.

Table 7. Trends and concepts for successful and failed technology transfers

Trends and Concepts for Successful Technology Transfers	Trends and Concepts for Failed Technology Transfers
<p>Having multilayer partnerships and collaborations with the private and public sectors increase the chances of having more successful technology transfer.</p>	<p>Conflict of interests within partnerships and collaborations can drastically lead to technology failures. This includes technical and business conflict of interests that involve intellectual property (IP) rights and ownership, investors, personnel and funding.</p>
<p>Understanding how the technology works early on within human subjects in clinical development greatly increases the chances of having more successful technology transfer.</p>	<p>The misalignment of the technical and business programs and practices within a technology transfer partnership can help challenge the success of the technology transfer project.</p>
<p>Building a robust technical and business intellectual property (IP) management process is a key entity to have success in technology transfer.</p>	<p>Comprising or ignoring the scientific, clinical, industry and regulatory facets of technology transfer will significantly inhibit the success of the technology transfer project.</p>
<p>Academia and industry collaborations that were not about monetary gains but getting a novel therapy approves the success of the technology transfer.</p>	<p>Perceptions of the technology transfer collaboration can have direct impact on the success of the technology transfer program.</p>
<p>Support from public sector including research funding, government funded research facilities and technology intellectual property ownership significantly has increased the success rate to have a successful technology transfer.</p>	
<p>Influences from the public sector including legislations and public funding have had a great effect on the success of technology transfer even with their debates.</p>	

Table 7 describes the trends and concepts for successful and failed technology transfers found among the case study analyses.

In support of these findings from the case studies, Cummings and Teng devised a research model for the success of technology transfer. Figure 7 describes this model devised by Cummings and Teng. This model includes key elements that affect the success of technology transfers between the research and industry areas and represents the areas that affect the knowledge and application of the technology involved in the transfer (Cummings, & Teng, 2003). This model is a good representation for the transfer, innovation and strategic management focal areas that need to be involved with the technology transfer. The model compliments that trends and concepts found in the case studies regarding successes and failures described in Table 7.

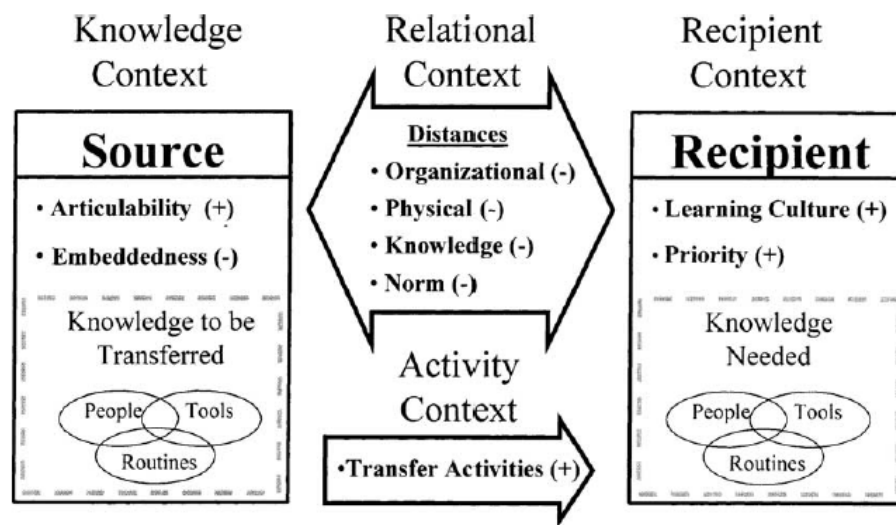


Figure 7. Research model for a successful technology transfer

Figure 7 depicts an illustration for a research model needed for a successful technology transfer from Cummings, & Teng, 2003.

A prime example of a collaboration that embraced this type of model was the collaboration between University of Pennsylvania, Children's Hospital of Philadelphia and Spark Therapeutics. This successful collaboration won approval for the first gene therapy, Luxturna (Sagonowsky, 2017), (Reddy, 2018). Even though the cost for this therapy is 425,000 per eye (\$850,000 total) which is the most expensive dose of a drug in the US and the approval of this therapy took almost 25 years, it demonstrated that novel drug therapies can be developed and commercialized with technology coming from academia (Sagonowsky, 2017), (Reddy, 2018). This collaboration demonstrated that success needs to not be about the technology transfer but about the partnerships. Figure 7 demonstrates this type of model representing the partnerships that need to occur for a successful technology transfer.

Legislation Impact on Case Studies

The impact of legislation on technology transfer between academia and the biotechnology industry also plays a supporting role in the success or failure of the case studies. As described by Greenbaum, critical legislations throughout history starting in the 1980s were passed to help promote the success of technology transfers between academia and the biotechnology industry (Greenbaum, 2009). This included the enactment of the Bayh-Dole Act which gave universities and businesses the right to maintain the title and intellectual property to their federally sponsored innovations. In addition, the enactment of Federal Technology Transfer Act enacted in 1986 aimed to institutionalize technology transfer in government laboratories and allowed federal laboratories in academia to negotiate licenses and patents for innovations discovered in the laboratory (Greenbaum, 2009).

These legislations were to help promote growth of developed novel technologies into drug therapies from academia to the biotechnology industry. In some cases, as evident with the collaboration between Kite Pharma (A Gilead Company), the National Cancer Institute and United States Government, it demonstrated that collaborations with federal institutions can help promote growth and success of technology transfers to commercial novel drug therapies (Pollack, 2016). The success for this collaboration was not just about the monetary gains that would come about the collaboration with federal institutions but about applying multiple collaborative within the technology transfer initiative to drive its success (Pollack, 2016).

However, the enactment of these legislations also demonstrated that it can have a negative effect on the success of technology transfers between academia and the biotechnology industry. As legislation increased to help promote the success of technology transfers between academia and the biotechnology industry, monetary incentives became more a focal point of the development of technology rather than the discovery of the technology itself (Begley, Buchan, & Dirnagl, 2015). A clear example of a conflict of interest due to monetary concerns based on government funding was the collaboration between Stanford and StemCell Inc. (Shanks, 2016), (Keshava, 2016). This collaboration focused on developing stem cell therapies and was funded by the California Institute for Regenerative Medicine (CIRM), a government agency funded by the state's taxpayers for further stem cell research (Shanks, 2016), (Keshava, 2016). A conflict-of-interest relationship occurred when the CIRM president resigned and joined the board of StemCells Inc in 2014. All federal funding provided to the Stanford and StemCell Inc. collaboration for the development of novel technologies for stem cell therapies became

compromised (Shanks, 2016), (Keshava, 2016). This conflict-of-interest relationship also compromised the research itself for the motives of the development of these therapies became clouded. It was clouded since the main intent of the collaboration was to produce novel technologies for stem cell therapies and not to just receive monetary benefits from government funding from the public sector (Shanks, 2016), (Keshava, 2016). This collaboration is a clear example of how legislation can help drive the success for technology transfers between academia and the biotechnology industry but then can have a negative effect on the development of the technology itself.

Interviews

During the interviews, themes were also discovered among the interviewees involving the reasons for success and failures within the biotechnology industry. As more interviewees were conducted, many themes became more apparent. The impact of these themes was evaluated as being high, medium and low. The criteria for evaluating the theme was high, medium and low was based on the repetition of the theme as it was discussed with the interviewees. Table 8 represents the common themes that were discussed during the interviews and its impact for the overall success of technology transfers.

Table 8. Themes discussed during the interviews for the challenges of technology transfer

Technology Transfer Themes During Interviews	Overall Impact
<p><u>Technical Challenges:</u></p> <ul style="list-style-type: none"> ▪ Reproducibility ▪ Robustness ▪ Technology processes <ul style="list-style-type: none"> ○ Raw materials, scalability and over-engineering ▪ Technology platform analytical and process standardization ▪ Structure of technology processes ▪ Technical documentation (technology record keeping) 	<p>Medium</p>
<p><u>Management Challenges:</u></p> <ul style="list-style-type: none"> ▪ Business and Quality Agreements ▪ Strategy ▪ Best Practices ▪ Communication ▪ Business Structure ▪ Expectation Differences ▪ Risk Management: <ul style="list-style-type: none"> ○ Quality risk, gap assessments and gap analyses 	<p>High</p>
<p><u>Personnel Challenges:</u></p> <ul style="list-style-type: none"> ▪ Time ▪ Commitment ▪ Preparedness ▪ Ownership ▪ Training / Experience ▪ Accountability ▪ Motive 	<p>Medium</p>

Table 8 describes the common themes discussed during in the interviews for the challenges of technology transfer.

Overall, management challenges seemed to have the greatest impact on the success for technology transfers. Within these management challenges, expectation differences and the lack of risk management seems to play the greatest role in having failures in technology transfers. Expectation differences and the lack of risk management within the technology transfer process was a common theme among discussed with all the interviewees. According to several interviewees, these were the key issues present in having success in a technology transfer process. Other management challenges also had impact which included lack of communication, lack of strategy and insufficient business and quality agreements between all parties involved in the technology transfer process. These all had a great supporting role in challenges with success in technology transfers.

In addition, both technical and personnel challenges were evident to have an overall medium impact to the success of the technology transfer. Within the technical challenges, there was consistency among that interviewers that technical challenges are very much present in the success for developing a success technology into a drug therapy. Technology process issues had the highest impact on the success for the technology transfer within the technical challenges. These technical process issues included challenges with raw materials, scalability issues with the technology and over-engineering the technology inhibiting its commercialization ability. All were evident to have great impact to the success of the technology transfer.

As for the personnel challenges, these elements were not as widely mentioned as to having the greatest impact on the success of the technology transfers. Motive, accountability and commitment were the lowest factors mentioned by the interviewees as having the greatest impact. However, lack of training and experience and insufficient

communication were mentioned multiple times with the interviewees as to being very impactful for the success of a technology transfers. These elements needed to constantly be addressed during the technology transfer process. In all, personnel challenges seemed have an overall medium impact on the technology transfer process.

Expectation differences, lack of risk management, technology process issues and lack of training / experience and communication were the most common themes discussed with the interviews to have the highest impact to technology transfer challenges between academia and the biotechnology industry. These topics were constantly discussed by the interviewees and were greatly emphasized as being the most impactful challenges for a successful technology transfer. Addressing these key factors upfront on the technology transfer process will significant increase the chances for having a successful technology transfer.

It should be noted that all these factors do have impact on the success for a technology transfer between academia and the biotechnology industry. These items are all intermingled with each other and all should be considered important to the success of a technology transfer. All topics discussed with the interviewees have importance to the technology transfer process and should be considered and evaluated during the technology transfer process. Some themes were more discussed more frequently and had more emphasis on them regarding the technology transfer process.

Considerations and Recommendations

Observed from the case studies and interviews, several considerations and recommendations came about for a successful technology transfer. These considerations and recommendations to help improve the technology transfer process between academia and the biotechnology industry are not novel concepts but are concepts that need to be revisited since they consistently demonstrate as being challenges for technology transfers. The compilation of these considerations and recommendations demonstrate that no method is ideal to help improve the technology transfer process, but multiple methods need to be considered to improve the process. This list demonstrates that to improve the technology transfer process and to have success multiple facets within the process must be improved. One element of the technology transfer cannot just be improved upon. A cumulative approach needs to be taken to improve each element to have success in improving the technology transfer process between academia and the biotechnology industry.

Table 9 represents the considerations and recommendations needed for a successful technology transfer. The source for the consideration and the recommendation is also provided in the table. This list is not all inclusive, but it highlights the important aspects that need to be considered for improving the success rate for technology transfer between academia and the biotechnology industry.

Table 9. Considerations and recommendations for a successful technology transfer

Considerations / Recommendations	Source (Case Study vs. Interview)
Improve the collaboration and partnership	Case Studies and Interviews
Involve a mentor with the technology transfer process	Interviews
Instill effective communication throughout the technology transfer process	Interviews
Collaborate with a strong financial partner with the collaboration and partnership	Interviews
Improve Business Agreements between parties at the start of the project	Case Studies and Interviews
Improve Quality Agreements between parties at the start of the technology transfer project	Case Studies and Interviews
Clearly define risk management processes including Quality risk, gap assessments and gap analyses	Interviews
Clearly define the expectations for each unit involved from the technology transfer	Interviews
Improve analytics of the technology including robustness, reproducibility and scalability	Case Studies and Interviews
Improve training and experience expectations	Case Studies and Interviews
Avoid conflict-of-interest issues including business and technical	Case Studies
Implement quality guidelines for the technology transfer process	Case Studies and Interviews
Transfer a technology with a platform already understood	Case Studies and Interviews
Involve the public sector including government funding and government research	Case Studies
Define the ownership the intellectual property (IP) and the success for development of the IP for commercialization for each milestone	Case Studies and Interviews

Table 9 describes the considerations and recommendations needed for a successful technology transfer found from the case study analyses and the interview findings.

One important concept that should be recognized as supporting the technology transfer process between academia and the biotechnology industry is the increasingly involvement of contract development and manufacturing organizations (CDMO) for the development of novel technologies including cell and gene therapies (Tate, 2017). CDMOs are currently being involved with identifying and developing key challenges of technology transfer process including the identification of cell line platform, creating master cell banks, identifying the sources for raw materials and developing production and purification methodologies for the transfer of novel technologies for meeting purity and safety requirements needed for quality regulations (Tate, 2017). The involvement of CDMOs within the technology transfer process has demonstrated to enhance and improve the technology process and the analytics needed to support the analytics. CDMOs have been pivotal in helping to move the technology process through its clinical phases while defining efficient processes for commercialization while overcoming strict regulatory requirements for commercialization (Tate, 2017). CDMOs are becoming one of the key elements to help drive the success of technology transfer in both academia and the biotechnology industry for CDMOs are completely aware of the technology process needing to bridge the gap between academia technology identification and industrial commercialization (Tate, 2017). This has been increasingly more important when developing and processing novel technologies or the developing of specialized drug therapies. This an important key in today's environment for technology transfers to have success.

Closing Thoughts

The transfer of technology between academia and the biotechnology industry in hopes to develop and commercialize a novel therapy is a very intricate, complex process that involves many facets. The challenges with technology transfers but can be attributed to multiple layers within the transfer process as well as legislative hurdles. Trying to solve all the challenges is unattainable. However, improvements can be made. Within this research, three successful case studies were analyzed that had success in transferring technology from an academia to the biotechnology industry in one or more steps of the process. In addition, two cases that had significant failures within the transfer process were analyzed. In conjunction with the case study analyses, eight academia and biotechnology industry experts that have direct experience in technology transfers were interviewed. These interviews provided direct insight into the challenges of technology transfers. At the end, it was hoped to gain some further insight into the challenges of technology transfers between academia and the biotechnology industry, pinpoint the specific areas that causing technology transfer to fail and gain possible recommendations and considerations that could help further the success of technology transfers. I believe this goal was met to hopefully provide the next technology transfer project with some guidance to having success.

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